UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

CHARLENE EIKE, *et. al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	Case No. 3:12-cv-01141-SMY-DGW
ALLERGAN, INC., *et. al.*,	)	
	)	
Defendants.	)	
	)	

DEFENDANT PRASCO, LLC'S MOTION FOR SUMMARY JUDGMENT AND BRIEF IN SUPPORT THEREOF

Defendant Prasco, LLC ("Prasco"), pursuant to Rule 56 of the Federal Rules of Civil Procedure, respectfully moves this Court for entry of summary judgment in its favor and against Plaintiff Shirley Fisher on all claims alleged against Prasco in this action. There is no genuine dispute as to any material fact, and Prasco is entitled to judgment as a matter of law. In compliance with Local Rule 7.1(c), Prasco submits the following brief in support of its motion:

I. INTRODUCTION

Plaintiff Shirley Fisher ("Fisher") asserted claims against Prasco on behalf of Illinois consumers ("Plaintiffs") who purchased two generic prescription eye drops medicines distributed by Prasco.[1] Fisher claims Prasco's practice of selling generic prescription eye drop medicines that emit eye drops greater than 15 microliters ("µL") violates the Illinois Consumer Fraud and Deceptive Business Practices Act ("ICFA"). 815 ILCS 505/1 *et seq.*.

It is undisputed, however, that Prasco merely distributes the medicines pursuant to Merck & Co., Inc.'s ("Merck") New Drug Application ("NDA") in accordance with a Supply and

[1] Ms. Fisher's claims against Prasco were joined as part of a larger putative class action involving several other named plaintiffs and Defendants. Ms. Fisher is the only plaintiff to assert claims against Prasco, and this motion is limited to those claims.

Distribution Agreement ("Distribution Agreement") between Merck and Prasco, filed under seal as **Exhibit A**. (First Amended Complaint, hereinafter "FAC," ¶¶ 30, 32–33). As such, federal and contractual law barred Prasco from designing or manufacturing the prescription eye drop medicines, or from now making the design changes Fisher seeks in this lawsuit. Accordingly, Prasco is entitled to summary judgment because: (a) Fisher's claims under the ICFA are preempted by federal law because federal law bars Prasco from making the design changes Fisher seeks; (b) Prasco could not have done the purportedly unlawful act of designing eye drops in excess of 15 µL; and (c) Fisher has no standing under Article III because Prasco cannot redress Fisher's alleged injury.

II. SUMMARY OF MATERIAL FACTS

A. Summary of Fisher's Claims.

The FAC identifies two Prasco products at issue—Dorzolamide Hydrochloride/Timolol Maleate (a generic of Merck's brand name drug Cosopt) and Dorzolamide Hydrochloride (a generic of Merck's brand name drug Trusopt) (collectively "the Products"). (*Id.* ¶ 33). Fisher alleges that Prasco unfairly sold the Products in bottles that dispense drops larger than the capacity of the human eye, which thereby produces waste because the excess solution either runs down the patient's cheek or drains through the tear ducts, in violation of ICFA. (FAC ¶¶ 193–197). Fisher alleges that Prasco utilizes a larger drop design to sell additional volume of the Products leading to increased profits for Prasco. (*Id.* ¶¶ 3, 75–77, 194). Fisher seeks compensatory and punitive damages, attorneys' fees, and declaratory and injunctive relief, including preliminary and permanent injunctions. (*Id.* at Prayer for Relief).

It is undisputed that Prasco is an Authorized Generic Distributor of the Products. Fisher alleges: "Among the Authorized Generic pharmaceutical products that Prasco distributes are two

products manufactured for it by Merck: Dorzolamide Hydrochloride/Timolol Maleate Ophthalmic Solution, which is identical to Merck's Cosopt; and Dorzolamide Hydrochloride Ophthalmic Solution, which is identical to Merck's Trusopt." (*Id.* ¶ 33). The FAC notes that Prasco only "distributes" the Products, which "are 100% identical to their brand-name equivalents because they are manufactured by the brand-name company and simply made available as a generic under private label." (*Id.* ¶ 32).

Fisher claims Prasco's distribution of the Products violated the ICFA. (*Id.* ¶¶ 13, 41, 133–152, 193–197). Thus, Fisher seeks both monetary damages and injunctive relief against Prasco—specifically, Fisher seeks to compel Prasco to change "the design and dimension of the dropper tip" of the eye-drop medications to reduce the drop size to a volume no larger than 15 µL per drop. (*Id.* ¶¶ 85, 88).

B. Prasco Merely Distributes the Products Under Merck's NDA.

Prasco sold the Products as an authorized generic distributor. (FAC ¶¶ 32–33). Prasco holds no NDA or ANDA for the Products, and merely distributes the Products under Merck's NDA. (Ex. A, p. 29).[2] Kirk Seeman, Prasco's Vice President of Supply Chain, explained at deposition:

> Q. Would it be agreeable if we called it "generic COSOPT" in this deposition?
> A. But "generic" would feel that you—that we would have actually filed an ANDA for this product. We didn't. It's an authorized generic, so it's actually the branded product sold as generic.
> . . .
> Q. So you are selling the product under the original NDA . . .is that right?
> A. Yes, we are.

[2] Section 11.1 of the Distribution Agreement states, "Merck shall have exclusive authority and responsibility for maintenance of the NDAs and the conduct of all regulatory actions with respect to . . . the FDA with respect to the NDAs and the distribution and sale of the Generic Product under this Agreement." (emphasis added)

(*See* Deposition of Kirk Seeman at 13:21–14:5, 16:21–24, filed under seal as **Exhibit B**). Mr. Seeman further confirmed that Prasco's sole role with respect to the Merck-manufactured Products was that of a distributor:

> Q. Is the product then exactly the same as the branded product except a different name on the label?
> A. That is correct.
> . . .
> Q. [B]ut the labeling that Prasco has or had for generic COSOPT was something that it obtained from Merck, correct?
> A. Yes. We received the original labeling from Merck and then my labeling group makes minor changes to the labeling, NDC number change, Prasco logo, and manufactured for Prasco. Those are the only changes that we are allowed to make.
> . . .
> Q. Under the agreement with Merck, Prasco was to buy, distribute and sell its requirements for generic COSOPT from Merck, correct?
> A. That is correct.
> . . .
> Q. Merck decided what the specifications would be for the products that it sold to Prasco, correct?
> A. Yes, that is correct.

(Ex. B, at 17:1–7, 22:17–23:7, 28:6–10, 34:16–19) (emphasis added).

C. The Distribution Agreement Limits Prasco to Distribution of the Products.

On January 16, 2007, Prasco and Merck entered into the Distribution Agreement. Under the Distribution Agreement's express terms and conditions, Prasco is required to distribute and sell the Products it obtains from Merck. (Ex. A, p. 8.) The terms of the Distribution Agreement unequivocally establish that Prasco's role with respect to the Products is specifically limited to that of a distributor—in pertinent part, the terms provide:

> Authorized Distributor: Merck hereby appoints Prasco to **market, distribute, offer for sale and sell the Generic Product in the Territory under the NDAs during the Supply Term** . . . on an exclusive basis, and Prasco hereby accepts such appointment. During the Supply term, **Prasco will purchase from Merck all of its requirements of Generic Product**.
> . . .

> Manufacturing: **Merck shall Manufacture** (or cause its Affiliate or Third Party to Manufacture) Generic Product which meets the Specifications, and in accordance with cGMP.

(Ex. A, pp. 8, 26) (emphasis added). Indeed, in various portions of the Distribution Agreement, the terms clearly state that Merck has the duty and responsibility of manufacturing and designing the Products. (*See e.g.*, Ex. A, p. 8, 16, 24, 26) ("Merck warrants that the Generic Product supplied by it hereunder shall, at the time of delivery . . . be Manufactured in compliance in all material respects with all other Applicable Law.").

Furthermore, the Distribution Agreement unambiguously states that Prasco is prohibited from making any modifications or alterations to the Merck-manufactured Products. (Ex. A, p. 9). Specifically, the terms state, in pertinent part:

> Compliance with Law: **Prasco shall . . . not alter the Generic Product in any manner**, including the labeling and packaging thereof . . . [and] not market the Generic Product in any manner which is inconsistent with the labeling of the Generic Product or Applicable Law, or otherwise make any false or misleading representations to customers or others regarding the Generic Product.

(Ex. A, p. 9) (emphasis added). Fisher has not presented, and cannot present, any evidence ascribing any role to Prasco other than as a distributor of the Merck-manufactured Products.

III. ARGUMENT

The material facts are undisputed: Prasco distributed authorized generic versions of the Products pursuant to Merck's NDA and their Distribution Agreement. The upshot is that Prasco had no legal authority to affect the size of the eye drops, nor can Prasco change the drop size of the Products in response to Fisher's claims. Because the undisputed facts establish that Prasco could not commit the allegedly unfair conduct asserted in the FAC, Prasco is entitled to judgment as a matter of law and this Court should award summary judgment in its favor.

A. Standard of Review

"Summary judgment is appropriate where there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law." *Lynnbrook Farms v. Smithkline Beecham Corp.*, 79 F.3d 620, 623 (7th Cir. 1996); Fed. R. Civ. P. 56(c). The mere existence of a factual dispute does not preclude summary judgment unless "the disputed fact is outcome determinative under governing law." *Egger v. Phillips,* 710 F.2d 292, 296 (7th Cir. 1983). In opposing a motion for summary judgment, the non-moving party must introduce more than mere conclusory allegations that are unsupported by specific facts. *First Commodity Traders v. Heinold Commodities, Inc.*, 766 F.2d 1007, 1011 (7th Cir. 1985); *Posey v. Skyline Corp.*, 702 F.2d 102, 105 (7th Cir. 1983).

B. Prasco is entitled to judgment as a matter of law because Fisher's claims under the ICFA are preempted by federal law.

Where state and federal law conflict, federal law prevails. *PLIVA, Inc. v. Mensing,* 131 S. Ct. 2567, 2577. A conflict exists when it is "impossible for a private party to comply with both state and federal requirements." *Id.* In *Mensing,* the Court specifically held that because federal law demands "that generic drug labels be the same at all times as the corresponding brand-name drug labels[,]" state tort claims against generic drug manufacturers are preempted because the companies cannot "comply with both their state-law duty to change the label and their federal law duty to keep the label the same." *Id.* at 2578. Thus, under *Mensing,* state law claims are only viable against entities that have unilateral authority under federal law to comply with the alleged state law requirement.

Mensing's progeny recognizes that distributors authorized to distribute brand-name drugs do not have authority to make changes to the products they distribute. *In re Fosamax (Alendronate Sodium) Products Liab. Litig.* (No. II), MDL 2243 JAP-LHG, 2012 WL 181411, at

*3–4 (D.N.J. Jan. 17, 2012)(dismissing plaintiff's state law defective design and failure to warn claims against a distributor because "[a]s a distributor of [a brand-name drug], [defendant] has no power to change [the] labeling").

Here, it is undisputed that Prasco sold the Products as an authorized generic distributor pursuant to Merck's NDA. (FAC ¶¶ 32–33). Prasco holds no NDA or ANDA for the Products. (Ex. A, p. 29). Accordingly, federal law prohibits Prasco from altering the Products' packaging, container closure system, or bottle dropper pursuant to 21 C.F.R. § 314.70. The power to submit supplemental applications to affect changes to approved drug applications rests solely with the applicant holder. *See* 21 C.F.R. § 314.71 ("Only the applicant may submit a supplement to an application."); 21 C.F.R. § 314.3 (defining "applicant" to be "any person who submits an application or abbreviated application . . ."). Federal law therefore prohibits Prasco from making the changes Fisher alleges Illinois state law requires—the definition of *Mensing* impossibility preemption. Therefore, Prasco is entitled to judgment as a matter of law on all of Fisher's claims.

C. The undisputed facts establish that Prasco was contractually prohibited from engaging in the "unfair practices" that Fisher alleges; thus, it cannot be held responsible for Fisher's alleged damages.

A foundational element in any unfair practice claim, including a claim asserted under the ICFA, is affirmative, wrongful action on the part of the defendant. To prevail under the ICFA, a plaintiff must prove: "(1) a deceptive or unfair act by the defendant; (2) the defendant's intent that the plaintiff rely on the deceptive or unfair practice; and (3) the unfair or deceptive practice occurred during a course of conduct involving trade or commerce." *Siegel v. Shell Oil Co.*, 612 F.3d 932, 934 (7th Cir. 2010) (emphasis added).

Here, the Distribution Agreement unequivocally demonstrates that Prasco's role with respect to the Products is contractually limited to that of a distributor. Pursuant to the express terms and conditions of the agreement, Prasco's sole duty is to distribute the Products Merck manufactures and supplies to Prasco.[3] (*See e.g.*, Ex. A, p. 8.) The terms of the Distribution Agreement establish that Prasco has no authority to modify the Products that Merck supplies. (Ex. A, p. 9) ("Prasco shall . . . not alter the [Products] in any manner."). Thus, pursuant to the contractual obligations and limitations of the Distribution Agreement, Prasco had no ability to alter the size of the eye drops, or modify the Products' container closure system and/or bottle dropper.

Accordingly, it is undisputed that Prasco, itself, did not engage in unlawful or "unfair" conduct as required by the ICFA. For these additional reasons, Fisher's claims against Prasco fail as a matter of law.

D. Prasco is entitled to judgment as a matter of law because Fisher has no standing under Article III.

"Any plaintiff seeking to invoke the power of a federal court bears the burden of demonstrating: (1) an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical; (2) a causal connection between the injury and the conduct complained of, that is, the injury is fairly traceable to the challenged action of the defendant, not the result of the independent action of some third party not before the court; and (3) a favorable decision likely will redress the injury." *O'Sullivan v. City of Chicago*, 396 F.3d 843, 853 (7th Cir. 2005). Prasco cannot redress Fisher's injury and therefore her claims fail as a matter of law.

[3] Plaintiffs concede that Prasco merely distributed the Products as "Authorized Generic" products in the same bottle as used by Merck. (FAC ¶¶ 32–33.)

Simply, Prasco cannot make the Products emit smaller eye drops. The Distribution Agreement and federal regulations prevent them from doing so. *See* 21 C.F.R. §§ 314.70, 314:71. Any insinuation by Fisher that this Court could somehow compel Prasco to change the "design and dimension of the dropper tip" is illogical and insufficient to establish Article III standing against Prasco. (FAC ¶¶ 85, 88, Prayer for Relief); *see Perry v. Vill. of Arlington Heights*, 186 F.3d 826, 829 (7th Cir. 1999) citing *Allen v. Wright*, 468 U.S. 737, 752 (1984) (noting that the prospect of obtaining relief from a favorable judgment must be "likely" and not "speculative"). Fisher's claims against Prasco lack Article III standing, because Prasco cannot redress Fisher's alleged wrongs. Accordingly, Prasco is entitled to entry of summary judgment.

IV. CONCLUSION

Fisher's claims cannot stand as a matter of law. The undisputed facts demonstrate that Prasco, as a mere distributor, and non-NDA, non-ANDA holder of the Products, was legally and contractually prohibited from engaging in the conduct that Fisher alleges amount to "unfair practices." Prasco did not, could not, and cannot, manufacture or modify the Products that allegedly gave rise to the injuries alleged in the FAC.

For these reasons, Prasco is entitled to entry of summary judgment in its favor on all claims asserted against in in the First Amended Complaint.

Dated: March 24, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of March, 2016, a true and correct copy of the foregoing document was served upon all counsel of record via the Court's electronic notification system:

/s/Stephen G. Strauss